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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,300	02/13/2002	Yoram Reiter	02/23339	6257

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 04/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/073,300

**Applicant(s)**

REITER, YORAM

**Examiner**

F. Pierre VanderVegt

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 4-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This application is a continuation-in-part of U.S. Application Serial Number 09/534,966.

Claims 1-11 are currently pending.

#### *Election/Restrictions*

1. Claims 4-11 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 8, 2004.

Accordingly, claims 1-3 are the subject of examination in the present Office Action.

#### *Response to Affidavit*

2. The declaration under Rule 1.132 of inventor Yoram Reiter filed December 27, 2004 has been fully considered. The substance of the declaration regards enablement of the claimed invention. It is unclear what purpose the declaration is supposed to serve, as it is irrelevant regarding any grounds of rejection of record in the instant application. Accordingly, the declaration will not be further addressed.

#### *Response to Arguments*

3. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

In view of Applicant's arguments, the previous rejection of record has been withdrawn. The following new ground of rejection has been applied and this Office Action is made NON-FINAL. Applicant's arguments are addressed as they apply to the new ground of rejection.

#### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is ambiguous and unclear in the recitation of "functional human  $\beta$ -2 microglobulin and a functional human MHC class I" in the claim. It is not readily apparent what "functions" the claim refers to. For example, is the function the ability to form a heterodimer, to bind a Class I-restricted peptide, to

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bind a cell membrane, to elicit an antibody response to the complex or to present a restricted peptide to a specific T cell? Clarification is required.

Claim 1 is ambiguous and unclear regarding the relationship of the "antigenic peptide" portion of the isolated chimeric polypeptide to the "functional human  $\beta$ -2 microglobulin" and "functional human MHC class I" portions of the isolated chimeric polypeptide. Is the "antigenic peptide" one that is specifically bound by the MHC class I elements of the same chimeric polypeptide, is the "antigenic peptide" one that is bound by a different MHC class I complex or is the "antigenic peptide" one that is bound by an antibody and not necessarily recognized by any MHC class I complex? Clarification is required.

Claim 1 is ambiguous and unclear in the arrangement of the elements of the chimeric polypeptide. Are the "antigenic peptide," "functional human  $\beta$ -2 microglobulin" and "functional human MHC class I" portions arranged in a specific order in the construct or is their arrangement freeform? Clarification is required.

Applicant should specifically point out the support for any amendments made to the disclosure.

See MPEP 714.02 and 2163.06

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mottez et al (J. Exp. Med. [1995] 181:493-502; U on form PTO-892, of record) in view of Lone et al (J. Immunotherapy [1998] 21(4):283-294; V on form PTO-892, newly cited).

Mottez teaches single chain constructs comprising a murine MHC class I heavy chain joined to  $\beta_2$ -microglobulin with a covalently bound antigenic peptide. Mottez teaches that linker, or spacer, sequences separate the segments (see entire document).

Mottez does not specifically teach human MHC class I heavy chain or  $\beta_2$ -microglobulin. However, in a continuation of the same work, Lone teaches that the same techniques were applied to human MHC class I heavy chain HLA-A2.1, which was joined via a 15-amino-acid linker to human  $\beta_2$ -

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microglobulin. Lone teaches that the single chain MHC class I construct folded properly and was functional (Abstract in particular). Lone teaches that the single chain MHC class I construct specifically bound HLA-A2 restricted peptides and induced peptide-specific cytotoxic T cells to proliferate and produce IL-2.

It would have been prima facie obvious to a person having ordinary skill in the art at the time the invention was made to substitute human MHC class I as taught by Lone for the murine MHC class I bound to a specific peptide as taught by Mottez. One would have been motivated, with a reasonable expectation of success by the showing of Lone that the human MHC class I complex associated with peptide and activated T cells as well as the murine MHC class I complex did. One would have been further motivated by the teaching of Mottez that single chain MHC class I complexes can be useful for manipulating an immune response, particularly to an antigen that has low affinity for the MHC molecule (page 501, 2<sup>nd</sup> column in particular).


### Conclusion


7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.   
Patent Examiner  
March 22, 2005

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182-1644